

# VIEWS & REVIEWS

## Ghost writers need to be more visible

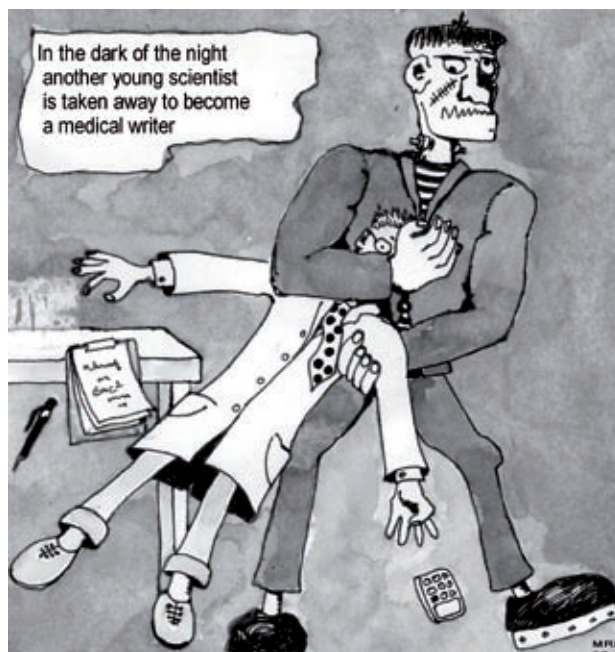
PERSONAL VIEW **Keith Dawes**

**M**edical writers contribute extensively to medical journals, mostly as unheralded “ghost writers.” They also have an important role in medical education, drug development, and drug marketing. Though mostly unseen, unappreciated, and misunderstood, they nevertheless add quite a bit of grease to the wheels of science publishing. It has been claimed that at least 50% of all publications on treatments in the *BMJ*, *Lancet*, and *New England Journal of Medicine* have been written by an unacknowledged ghost writer (*BMJ* 2004;329:937; 2004;329:1345).

Given the negativity associated with publications sponsored by the drug industry, the hidden role of the medical writer has attracted much criticism. The preconception that medical writers are all unscrupulous—employed by Machiavellian drug companies to distort and promote scientific data in an unethical manner—is untrue. Most medical writers would welcome more recognition; and in an effort to increase transparency several publication guidelines recommend that papers acknowledge medical writers.

My experience is that authors and sponsors are profoundly reluctant to take this simple step—perhaps through embarrassment or ignorance or just to maintain the historical status quo that medical writers are not acknowledged. It seems that any overt association with a sponsored medical writer detracts from the work or from the named authors. Or perhaps it emphasises too strongly a third party who might distort data for their employer?

Unfortunately, data manipulation and publication misconduct do occur in all fields of research (whether industry sponsored or not) and at all levels, and identifying “doctored” papers is a major concern for journal editors. Drug



companies are under huge pressure to publish positive results for their drugs, and much money is spent in planning and preparing a publication programme for a major marketed compound. This commercial pressure fosters data manipulation or, more commonly, data suppression. This is not predetermined but occurs because of the personalities involved in preparing a scientific paper. Professional medical writers should never encourage data manipulation or divergence from the accepted practices of scientific publishing, such as those outlined by the Committee on Publication Ethics ([www.publicationethics.org.uk](http://www.publicationethics.org.uk)), but I am sure that a minority have, under pressure, contributed to such bad practice. Clinicians and scientists occasionally “spin” results, pick their publications strategically, and neglect to (or cannot) publish negative data.

The medical writer may have prepared 90% of the paper, but he or she does not have a final say on its contents. This is always at the discretion of the authors or sponsor after all data have been reviewed. Horror stories of papers written

without authors’ consent have emerged (*Guardian*, <http://education.guardian.co.uk>, 21 Apr, “Not in my name”), but I have no personal experience of this. Moreover, production of poorly written or erroneous papers is actively discouraged, as the repercussions for the drug and the company involved can be serious.

Many publication managers have a marketing background and don’t fully understand or embrace the principles of scientific publishing, hence medical writers often act as educators and have to balance the different viewpoints of authors and sponsors.

Medical writers’ contribution to health education is appreciated by some, but the general feeling of circumspection concerning their motives remains. Unfortunately, this circumspection lends support to the conspiracy theorists. Positive efforts are needed to bring clinicians, scientists, drug companies, and medical writers into more contact, perhaps through professional societies. Greater pressure from journals to acknowledge medical writers would also be a positive step, particularly if applied to drug companies.

We should be sending the message that it is not bad practice to use a professional writer and that it is even better to admit doing so. Medical writers are not a fifth column but are working in a fast moving, modern environment to help disseminate scientific information. They are here to stay, and their work needs to be embraced and acknowledged to increase the transparency of public information.

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What medical and  
psychiatric staff could  
learn from R D Laing's  
*The Divided Self*,  
p 211



# Inside big pharma's box of tricks

**Joe Collier** is impressed by a documentary about the marketing of paroxetine

The list of examples of big pharma's trickery seems endless (even though many of those employed in it are of the highest calibre and of unquestionable integrity). Indeed, it is as though, in the marketing arm of some drug companies, mischief is institutionalised. But much of this is recognised, and the adverse effects of drug companies could be countered by alert regulators, scientists, prescribers, and the medical press. All too often, however, these checks fail. There is even evidence that, in some cases, these counter-forces collude with industry and so compound its indiscretions. It is this area, the interplay between industry and some of the would-be counter-forces, that *Panorama's* "The Secrets of the Drug Trials" seeks to tackle.

*Panorama* has been investigating drug companies' behaviour for years, and this inquiry is its third involving selective serotonin reuptake inhibitors (SSRIs), and in particular Seroxat (paroxetine), since 2002. It deals primarily with GlaxoSmithKline's history as it relates to the development of paroxetine for the treatment of children with depression. Drawn into the frame are opinion formers and medical journals, and the picture painted is one of a conspiracy orchestrated by the company in which doctors have been misled, regulators duped, journals exposed, and children harmed.

The story is said to be based on information gained from "secret" company files made available through court cases and freedom of information regulations. It starts with the company discovering the results of trials it has commissioned to investigate the value of paroxetine in the treatment of adolescent depression: the product was found to be no more effective than placebo and able to cause serious psychological side effects such as self harm, suicidal thoughts, and suicidal attempts.

At the time the company had wanted to license the drug for use in depressed children but privately realised that with such information an application would be unsuccessful. The inquiry then tells of how the company is claimed to have "written up" the trial for publication, bought and manipulated (apparently willingly) opinion formers, worked to promote the product for use in children (although it was not, and never has been, licensed for such use), and distorted information about the safety and efficacy of the drug in letters to prescribers, in advice to their sales force, and in messages to the media.

The programme claims there was a failure by the company to reveal material about Seroxat to the regulatory authorities and a failure by the regulatory authorities to recognise and respond to the various problems with due

speed. But these are areas in which *Panorama* has investigated before. It is the pursuit of media manipulation that now gets particular attention. The inquiry claims that the manufacturer, through its agencies, "ghost wrote" the major trial that was subsequently published in the *Journal of the American Academy of Child and Adolescent Psychiatry*, and how that in the "writing" data were distorted to maximise the known benefits and minimise known harms. It also reports that key named authors of the paper do not appear to have critically read the report; how the journal editors had failed to spot the distortions (although at least one other medical journal had been concerned enough to reject the article earlier); how key opinion formers "promoting" the product were so close to the company financially and intellectually that they could not possibly offer independent advice; and how drug company spokespeople simply lied to the media when pressed about the product's side effects.

If these claims are well founded, patients deserve better. *Panorama* has made its contribution by telling this story. It has reminded us again of a social contract involving drug producers, drug prescribers, drug regulators, and information suppliers. In a properly functioning society, openness and honesty should be assumed and certain standards of behaviour expected. Indeed, in an ideal world, drug companies should be trusted. It has to be recognised that not all activities can be controlled through legislation; rather they rely on good practice and honesty and a will not to cheat patients.

It does seem that regulatory authorities now appear more prepared to tackle these issues and prescribers have greater insights into drug company behaviour and have every reason to be vigilant. For their part, professional bodies must start to look seriously at how their members behave and bring to book those who mislead (or collude in misleading) others about drug properties.

The new players to enter the equation are the medical journals. These provide a crucial conduit between drug companies and society at large as they publish original papers, opinion pieces, and, of course, advertisements for drugs. Many are suspicious of the media, but as is often the case it is the media (and typically *Panorama*) that will have been important in prompting much needed change. It seems silly that we should need the media to shame us into altering our ways; surely we should be proactive and get there first.

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## REVIEW OF THE WEEK

**Panorama: The Secrets of  
the Drug Trials**

BBC 1, 29 January  
at 8 30 pm

Rating: ★★☆☆

**Professional bodies  
must start to look  
seriously at how  
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behave and bring  
to book those who  
mislead (or collude  
in misleading)  
others about drug  
properties**

# A union to preserve

FROM THE  
FRONTLINE  
Des Spence



The Scottish medical mafia are everywhere. Only warily do they include me, despite my mother having been born in Edinburgh and my having lived in Scotland since my early childhood. My English accent and my passport showing Saffron Walden as my place of birth mark me as an outsider. However, I know the important social codes. I can name Scotland's World Cup squad of 1978, I am word perfect with both *Ally's Tartan Army* and *Flower of Scotland*, I can dance at ceilidhs, recite Burns, enjoy a wee dram, and can sing the chorus of any country and western song you care to name.

At Burns nights around the world Scottish doctors will toast the baird, and with 300 years since the Act of Union there will be much talk of independence. Does it matter if Scotland goes it alone? Many people in England frankly don't care and are tired of the perceived griping and bottomless anti-English sentiment. Scotland in turn remains angry and resentful of perceived English dominance. So perhaps it is time to end our unhappy civil union, both sides citing unreasonable behaviour and irreconcilable differences.

But marriage is an enduring institution. Scotland is far from being one place, and the two countries have much more in common than we think. The ugly sisters Glasgow, Manchester, and Liverpool were born to the same heavy smoking, violent Victorian industrial father. The windswept north of Scotland and the

Western Isles have more in common with the remote wilds of England than with Scotland's central urban belt. Haughty Edinburgh (pronounced "England-burgh" in the west) is a match for the snobbery of the Home Counties. But going deeper than this we have a shared history, and both peoples were conscripted to fight in the same wars or were worked to death in equal measure across the centuries by the oppressors, a small Anglo-Scots oligarchy. Lastly, we share a wonderfully complex culture of cynicism, understatement, and dark sarcasm (likewise our siblings the Irish and Welsh). We British doctors stick together abroad because neither the North Americans nor the Europeans—and not even the Antipodeans—ever quite "get it."

If we do decide to get divorced, let's do it for the right reasons, not for some one night stand of nationalist lust. With independence, we might be better off, happier, and more respectful of each other. But we have much to lose. What would become of the NHS, an institution riddled with Scots? Would we see an end to our historical trade in medical expertise? Within the NHS the Scots' strong sense of egalitarianism and community has long been a foil to the free market English. Let's not let Margaret Thatcher, the poll tax, 1966, and the North Sea oil issue blind us to the fact that we need each other, even if we may not always appreciate each other.

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# The new jetsetting

OUTSIDE THE BOX  
Trisha Greenhalgh



Last week, I received six separate invitations to speak at conferences abroad. One agreed to reimburse my economy class air fare if I couldn't pay it myself. Another promised a business class flight, chauffeur driven limousine on the ground, a personal bodyguard if I wanted to check out the local night life, and a generous honorarium with tax all sorted. The others offered various packages and incentives in between.

I turned them all down, mainly because in these days of global warming, I am finding it increasingly difficult to justify going half way around the world to give a talk that other people are going halfway around the world to listen to.

Let's be clear: I'm not saint when it comes to my carbon footprint. I'm off next month on what is

colloquially known as a "freebie"—two lectures and a workshop in return for a week in a luxury hotel overlooking a mile of private beach. I usually drive the three miles to work. I run my dishwasher and washing machine 21 times a week. I've never got round to finding the right low energy light bulbs for my non-standard sockets. All this behaviour has gone into my new year's resolution box, and if you're interested, I'll report progress on mending my ways in a few months' time.

Back to the conference scene. I contacted the organisers of one event and offered to do my lecture by video link—not because I especially wanted to prepare a talk for which I would not now be paid and find a technician willing to get up at 4 am to help me beam it across to New Zealand, but because

I figured it was time I did my bit to change the "freebie" culture for international speakers. My email probably read like the response of a B-list celebrity who can't be fagged to pick up her own Oscar, but to their credit, the organisers have put my offer on the agenda for their next planning meeting.

If all goes well, I will deliver my talk live, and take questions from the audience, without leaving my office in London. But all this depends on delegates agreeing to a shift in the definition of a "quality" conference such that Professors A, B, and C do not need to be wheeled on, in the flesh, to give keynotes before anyone is allowed to get started on sharing research findings.

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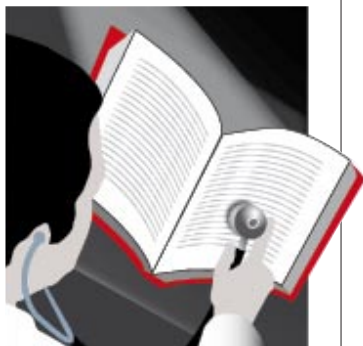
# Contemplating annihilation

Humans are the only creatures capable of contemplating their own annihilation as a species; moreover, they do so with something akin to pleasure, to judge by the frisson that literary and cinematic annihilations usually evoke. For example, I once saw a film in the Teatro Municipal of Uyuni, on the Bolivian altiplano, in which giant spiders invaded the Earth from outer space and threatened to destroy the whole of humanity. Only the US Air Force stood between the spiders and human extinction, and the audience cheered the spiders on to victory—though whether this was misanthropy or mere anti-Americanism I cannot be absolutely sure. At any rate the survival of humanity at the end of the film came as great disappointment to the audience.

Now, H G Wells was a man with a great deal of scientific intuition: he had a finely attuned nose for future developments. Of course, his faculty of self knowledge was rather less well developed, and in a book of essays entitled *Certain Personal Matters*, published in 1898—in which among many other subjects he discusses the future of mankind from the annihilationist perspective—he rails against the art of conversation, starting his essay on the subject with the admission that “in conversation I am not a brilliant success,” but admitting nowhere that one of the reasons for this, perhaps indeed the principal reason, was his squeaky voice.

In his essay “The Extinction of Man” Wells points out that “in no case does the record of the fossils show a really dominant species succeeded by its own descendants.” Wells imagines various successors to humans as the dominant species, such as giant crabs (at the end of

## BETWEEN THE LINES Theodore Dalrymple



**A prophet of doom is without honour in his own calamity**

his novella *The Time Machine* they appear by AD 35 000 000 to have inherited the earth) or insects such as army ants (I once saw a film in which insects were the only terrestrial fauna to have survived a nuclear war).

At the end of the essay comes one of Wells's startling scientific predictions: startling because the germ theory of disease was comparatively new when he made it. “And finally there is always the prospect of a new disease. As yet

science has scarcely touched the fringe of the probabilities associated with the minute fungi that constitute our zygotic diseases. But the bacilli have no more settled down into their final quiescence than have men; like ourselves, they are adapting themselves to new conditions and acquiring new powers.”

He goes on to say, “Even now we may be quite unwittingly evolving some new and more terrible plague—a plague that will not take ten or twenty or thirty per cent, as plagues have done in the past, but the entire hundred.”

Is this not the theme of more than one best selling airport novel, and has not the idea caused more than one public panic in the past few years? AIDS, Ebola virus, severe acute respiratory syndrome, avian flu—do we not imagine one of them wiping us all out sooner or later?

However many times the catastrophe fails to happen, we think it might happen next time. And when it does, and the human race is facing extinction, one may doubt, as Wells observes, whether even then he, Wells, will get the recognition he deserves. A prophet of doom is without honour in his own calamity.

Theodore Dalrymple is a writer and retired doctor

## MEDICAL CLASSICS

**The Divided Self** By R D Laing

**First published 1960**

In his short life the Scottish psychiatrist Ronald (“Ronnie”) Laing progressed from iconoclast to guru and mystic. *The Divided Self* was written at the beginning of this journey, when he was only 30. He went on to write other books in which he expressed some of the main tenets of the anti-psychiatry movement, including the belief that madness can be a useful interpersonal strategy or even a healing process rather than an illness—but this first book is probably his best.

In it he describes with empathy some of his patients and concludes that those who developed schizophrenia did so because of disturbed family relationships. Although like Freud he regarded schizophrenia as a disorder of ego identity, his book made schizophrenic symptoms—often regarded as incomprehensible—seem understandable for the first time within the family context. Some people who read *The Divided Self* became psychiatrists as a result, and the book had a considerable influence on the culture of the 1960s and 1970s (think of *One Flew Over the Cuckoo's Nest*, for example).

*The Divided Self* can be summarised briefly. Abnormal family relationships can in some cases result in the development in the child of “ontological insecurity,” a schizoid personality,



**Iconoclast, guru, and mystic**

and, eventually, frank psychosis, usually in adolescence or later. The “self” of the child cuts itself off from other people and starts to relate only to itself so that it can maintain its identity and protect itself from external danger. The self comes to hate the world but also feels guilty because it thinks it does not deserve to be alive. The self may then attempt to destroy itself—or may split and then relate only to its false self (the self that complies empty with the world). In psychosis the self can disintegrate into several parts or subsystems, which persecute what is left of the real self. In the end the self may no longer exist at all, but only what one patient poetically described as “the ghost of the weed garden.”

Since Laing wrote his book we have evidence of genetic factors, structural brain damage, and intellectual dysfunction in schizophrenia. This does not, of course, exclude the possibility that social factors, including the influence of the family, could play a part. Probably the real value of *The Divided Self* is ethical rather than scientific. Laing treated his patients with great respect, and trying hard to understand them was part of this. Psychiatric patients are still stigmatised today, even by medical and psychiatric staff, who could learn something fundamentally important from this book.

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